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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,485	01/30/2006	Katrin Kriwet	33300-US-PCT	5777
1095	7590	12/05/2007	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			THOMAS, TIMOTHY P	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,485

Applicant(s)

KRIWET, KATRIN

Examiner

Timothy P. Thomas

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-19 is/are pending in the application.
- 4a) Of the above claim(s) 6, 9, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-17 is/are rejected.
- 7) ☒ Claim(s) 10 and 12-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/30/2006, 7/27/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 10/22/2007 is acknowledged. The traversal is on the ground(s) that the common technical feature (lavendustin and an emollient) is patentable over Nussbaumer (US 5,990,116; IDS 7/27/2006 reference AA) and Kameshwari ("Sensory properties of Emollients"; 1999; Cosmetics & Toiletries; 114(1): 45-51; IDS 7/27/2006 reference AS), that a person skilled in the art would not combine Nussbaumer and Kameshwari in such a way to produce the present common technical feature; specifically Nussbaumer does not disclose the use of an emollient, nor recognize that lavendustin derivatives cause skin irritation and Kameshwari does not disclose the use of emollients in pharmaceutical formulations nor that emollients can decrease the skin irritant properties of pharmaceutically active compounds, particularly lavendustin derivatives. This is not found persuasive because one of ordinary skill in the art would use an emollient as or in a carrier for the active compound of formula I; when used for topical application, with the added benefit of softening the skin and making it more pliable by increasing tissue moisture content (see Gennaro, et al., Ed.; 2000; in "Remington: The Science and Practice of Pharmacy", 20th Edition; p. 1204, "Emollients" section, 1st and 4th paragraphs). Such added therapeutic benefit of emollients are specific characteristics that would motivate one of ordinary skill in the art to utilize the emollients of Kameshwari in the topical ointments and creams for the treatment of psoriasis and other skin conditions taught by Nussbaumer (col. 25, lines 39-41, 65-66). In fact, a number of

ointments and creams, well known in the art, contain emollients (see, for example, Gennaro, p. 1036, "Hydrophilic Ointment" formulation, which contains 25% white petrolatum) and Gennaro teaches "therapeutically, ointments function as protective and emollients for the skin, but are used primarily as vehicles or bases for the topical application of medicinal substances" (p. 1034; "Ointment Bases" section, 1st paragraph). While the motivation to combine would not be the same as applicant's reason for the invention (cosmetic/therapeutic skin softening and enhanced pliability and an emollient or an ointment or cream containing an emollient makes an excellent carrier for the active ingredient vs. the specific irritation caused by lavendustin derivatives and the reduction of that irritation when an emollient is used); the ordinarily skilled artisan would have been motivated to combine the teachings to produce the technical feature of the instant claims. Alternatively, the quotation from Gennaro above (p. 1034) supports the position that Nussbaumer alone, in teaching topical ointments, implies the presence of an emollient with the active compound (see rejection below under 35 USC 102(b)), i.e., Nussbaumer alone disclosed the technical feature of the instant claims.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6, 9, 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/22/2007.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Topical Pharmaceutical Compositions of Lavendustin Derivatives.

Claim Objections

4. Claims 10 and 12-14 are objected to because of the following informalities: in claim 10 the phrase "fatty acids" is repeated twice in lines 3-4; in claim 13 the word "accordingly" is not proper grammatically; in claim 12 there is a missing word, "the" or "said", before "emollient"; in claim 14 there is a missing word, "the" or "said", before "hydrophilic". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
7. Applicant does not have written support for the combination of emollient ingredients of the claim. The claims are drawn to a composition comprising a

lavendustin derivative of formula I, an emollient, optionally a hydrophilic component and optionally water, where the emollient comprises ingredients recited from (i) "liquid fatty alcohols, ..., propylene glycol ricinoleate, and propylene glycol stearate" (a complex mixture, containing more than 19 ingredients), or (ii) petrolatum, or (iii) mixtures thereof ((i)+(ii); containing more than 20 ingredients). Applicant has not disclosed any such complex mixture as (i) or (iii) as the emollient of a composition in the specification. Therefore, the claim introduces new matter. (It is noted that applicant has provided written description for (ii), petrolatum.)

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5, 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. The term "high local concentration" in claim 5 is a relative term which renders the claim indefinite. The term "high local concentration" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is not clear where the metes and bounds of the claim fall with respect to avoiding a high local concentration of lavendustin.

11. Claim 5 recites the limitation "the lavendustin" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites "a lavendustin derivative of formula I", the formula given is a different structure than lavendustin. "The lavendustin" (not the lavendustin derivative) of claim 5 refers to a different compound than in claim 1, on which claim 5 depends, and therefore does not have antecedent basis. For the purposes of prior art rejections it is assumed that applicant intended the phrase in claim 5 to read "the lavendustin derivative."

12. Claim 10 contains the trademark/trade name Miglyol® 812. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a specific emollient and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 1, 3, 5, 11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nussbaumer (US 5,990,116; IDS 7/27/2006 reference AA).

Nussbaumer teaches the elements of the claims: active compounds of instant formula I, including the elected compound (the specie of claim 17; column 22, line 22); topical formulations in conventional forms, including creams and ointments (col. 25, lines 65-66); concentrations of the elected formula I compound from 0.5-5% (col. 26, lines 4-5). Gennaro, et al., Ed. ("Remington: The Science and Practice of Pharmacy", 20th Edition; 2000, p. 1034) teaches "therapeutically, ointments function as protective and emollients for the skin" (p. 1034; "Ointment Bases" section, 1st paragraph) and emulsion bases may be termed creams or lotions (p. 845, 3rd paragraph); therefore the teaching of the active agent in a topical ointment is a teaching of an emollient present with the active agent and the teaching of a cream also implies and emulsion, anticipating the claims.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 1-5, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nussbaumer (US 5,990,116; IDS 7/27/2006 reference AA) and Gennaro, et al., Ed. ("Remington: The Science and Practice of Pharmacy", 20th Edition; 2000) in view of Marks ("Adjuvant Treatments and Other Medicaments in the 'Gray' Area between Medicine and Toiletries"; 1995; in Principles of Pharmacology: Basic Concepts & Clinical Applications; Munson, et al., Eds.; Chapman & Hall: New York; Chapter 78; "Emollients" section).

18. Nussbaumer teaches active compounds of instant formula I, including the elected compound (the specie of claim 17; column 22, line 22); topical formulations in conventional forms, including creams and ointments (col. 25, lines 65-66); for use as anti-inflammatory agents in skin conditions, such as psoriasis (col. 25, lines 34-41); concentrations of the elected formula I compound in the range of 0.5-5% are taught for topical formulations (col. 26, lines 4-5). Nussbaumer does not teach any specific emollients, hydrophilic components, or water or concentrations of such compounds or forms, other than a general reference to creams and ointments. Gennaro teaches emollients (softeners or moisturizers) increase tissue moisture content, thereby

rendering the skin softer and more pliable (p. 1204, Emollients, 1st paragraph); are chiefly used, beyond their therapeutic actions, to provide vehicles for lipid-soluble drugs (such as ointments and liniments) (p. 1204, Emollients, 4th paragraph); when the oil: water partition coefficient is greater than 1.0, the penetration is retarded and the emollient vehicle prolongs the action of the active ingredient (at the concentrations of active agent taught by Nussbaumer, would result in "avoiding high local concentration of the" active agent "in the skin or mucous membrane"; p. 1204, right column, top paragraph); specific emollients taught include isopropyl myristate (p. 1204, under "Other Emollients") and petrolatum (p. 1204, under "Animal Fats and Oils"); hydrophilic components taught include polyethylene glycol 400 (a liquid PEG; p. 847, 4th paragraph from end) and propylene glycol (p. 1036, under "Hydrophilic Ointment"); as well as purified water (p. 1036, under "Hydrophilic Ointment"); forms include oil-in-water and water-in-oil emulsions (p. 845, 2nd paragraph; by far the majority of commercial dermatologic drug products are formulated in an emulsion or cream base, which are washable and removed easily from skin or clothing (p. 846, right 4th paragraph); one specific formulation taught is the Hydrophilic Ointment (and oil-in-water emulsion; p. 1036), which contains emollient (white petrolatum) at 25%, hydrophilic component (propylene glycol) at 12%, and water at 37%; even after introducing the active compound at up to 5% the claimed components would still be present in amounts that fall within the claimed ranges. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the active compound within the concentration range taught by Nussbaumer in the ointments and creams of Gennaro using the

emollients, hydrophilic components and water taught by Gennaro to make the topical pharmaceutical compositions of the claims. The motivation to combine is taught by Gennaro: 1) to soften and moisturize the skin and 2) to provide a suitable topical vehicle for the compound of Nussbaumer. An additional motivation to combine the emollients and other compounds of Gennaro with the active compound of nussbaumer is taught by Marks: in addition to moisturizing, softening and smoothing of the surface of the skin and decreased scaling (p. 1219, 2nd paragraph), emollients have "anti-inflammatory" therapeutic effects (p. 1219, right, 2nd paragraph) and are useful in both inflammatory and non-inflammatory dermatoses, such as eczema and psoriasis to relieve symptoms, to reduce scaling and fissuring and to assist in damping down the inflammatory process (p. 1220, 4th paragraph). Since the anti-inflammatory properties of emollients are in common with anti-inflammatory agents of Nussbaumer, the skilled artisan would have been motivated to use the emollients in and as vehicles in topical formulations of the elected compound for the additional anti-inflammatory properties for skin conditions, such as psoriasis. There would have been an expectation of success in the preparations.

A characteristic of a topical pharmaceutical composition comprising the same active compound with the same emollient, hydrophilic compound at concentrations within the claimed ranges would have been that the formulation is "well tolerated". Alternatively, it would have been obvious to conduct routine optimization to modify the components and adjust concentrations so that the formulation would be "well-tolerated". The motivation to optimize the composition is suggested by Gennaro, "an ointment base

functioning as a drug vehicle should be optimized for a specific drug and, insofar as possible, for specific disease states or skin conditions" (p. 845, 4th paragraph).

Conclusion

19. No claim is allowed.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/TPT/
Timothy P. Thomas
Patent Examiner

Ardin H. Marschel 12/3/07
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